In the Claims

1. (Cancelled)

2. (Cancelled)

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30. (Cancelled)

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34. (Cancelled)

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37. (Cancelled)

38. (Cancelled)

39. (Previously Presented) A sleep regulating pharmaceutical formulation for oral administration before bedtime, comprising:

a first component providing an initial prompt release of a sleep-compatible substance for effecting the onset of drowsiness and slumber,

a second component containing at least one pharmaceutical wakeup agent, and

a third component for delaying the delivery of the wakeup agent of the second component for a period of time corresponding to a nominal interval of sleep.

40. (Previously Presented) A sleep regulating pharmaceutical formulation for oral administration before bedtime, comprising:

an outer component providing an initial prompt release of a sleep-compatible substance for effecting the onset of drowsiness and slumber,

an inner subsystem located within said outer component comprising a core containing at least one wakeup agent; and

a coating completely enveloping said core for delaying, the delivery of said wakeup agent of the core for a period of time corresponding to a nominal interval of sleep.

41. (Currently Amended) A sleep regulating pharmaceutical formulation as set forth in claim ~~[32]~~ 40, wherein said sleep-compatible substance is selected from the group consisting of tonics, calmatives, hypnotics, muscle relaxants, sedatives, anti-anxiety agents, anti-insomnia agents, tranquilizers, hormones, endorphins, herbal preparations, and substances having soporific effects.

42. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said sleep-compatible substance is selected from the group consisting of benzodiazepines; non-benzodiazepines; eszopiclone (S-Zopiclone) NGD 91-2, NGD 96-3, and NS2710, and indiplon (NBI-34060).

43. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said sleep-compatible substance is selected from the group consisting of benzodiazepines, lorazepam, temazepam, triazolam and their derivatives; non-benzodiazepines, zaleplon, zolpidem tartrate, L -tryptophan, 5-hydroxy-L-tryptophan, melatonin, eszopiclone (S-Zopiclone) NGD 91-2, NGD 96-3, and NS2710, and indiplon (NBI-34060).

44. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said inner subsystem includes a gas-generating substance for generating a gas upon reaction with water.

45. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said inner subsystem includes a gas-generating substance and an acid for generating a gas upon reaction with water.

46. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said inner subsystem includes a gas-generating substance selected from the group consisting of sodium bicarbonate, calcium carbonate; and
a mild acid selected from the group consisting of citric acid and sodium dihydrogen phosphate.

47. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said inner subsystem is an agglomeration of smaller subunits.

48. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in

claim 40, wherein said wakeup agent is an agglomeration of smaller subunits of said wakeup agent; and

each of said smaller subunits of said wakeup agent being individually enveloped by a coating.

49. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said wakeup agent is selected from the group consisting of pharmaceutically active energizers, invigorants, nervous system stimulants, and psychostimulants.

50. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said wakeup agent is selected from the group consisting of amphetamines, methylphenidate, venlafaxine, nefazodone, sodium oxybate, adrafinil, modafinil, phentermine, pemoline, adrenaline and methyl xanthines.

51. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said wakeup agent is caffeine.

52. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said coating comprises an osmotic semipermeable membrane.

53. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said coating comprises an osmotic semipermeable membrane impermeable to said wakeup agent.

54. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said coating comprises an osmotic semipermeable membrane impermeable to said wakeup agent; and

said osmotic semipermeable membrane being permeable to water for enabling progressive expansion of said osmotic semipermeable membrane by internal pressure in the gastrointestinal tract to burst said osmotic semipermeable membrane for releasing simultaneously substantially all of said wakeup agent.

55. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said coating comprises an osmotic semipermeable membrane impermeable to said wakeup agent;

said osmotic semipermeable membrane having a weak spot ; and

said osmotic semipermeable membrane being permeable to water for enabling progressive expansion of said osmotic semipermeable membrane by internal pressure to burst said weak spot of said osmotic semipermeable membrane for releasing simultaneously substantially all of said wakeup agent into the gastrointestinal tract.

56. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said coating comprises an osmotic semipermeable membrane impermeable to said wakeup agent;

said osmotic semipermeable membrane having a seam ; and

said osmotic semipermeable membrane being permeable to water for enabling progressive expansion of said osmotic semipermeable membrane by internal pressure to burst said

seam of said osmotic semipermeable membrane for releasing simultaneously substantially all of said wakeup agent into the gastrointestinal tract.

57. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said osmotic semipermeable membrane is selected from the group consisting of organic cellulose esters; inorganic cellulose esters; cellulose ethers; vinyl esters; polyvinyl alcohols; polyurethanes; and polyacrylics.

58. (Previously Presented) A sleep regulating pharmaceutical formulation as set forth in claim 40, wherein said osmotic semipermeable membrane is selected from the group consisting of cellulose acetate; cellulose nitrate; ethylcellulose; polyvinylacetate and ethylene vinyl acetate.

59. (Currently Amended) A sleep regulating pharmaceutical formulation for oral administration before bedtime, comprising:

an outer component providing an initial prompt release of a sleep-compatible substance for effecting onset of drowsiness and slumber,

an inner subsystem comprising a core containing an agglomeration of small wakeup agent subunits gas-generating substances;

said gas-generating substances for generating gases upon reaction with water;

a coating comprising an osmotic semipermeable membrane impermeable to said wakeup agent covering each of said agglomeration of small wakeup agent subunits and said gas-generating substances; and

said osmotic semipermeable membrane being permeable to water for enabling water in the gastrointestinal tract to react with said gas-generating substance to progressively expand said osmotic semipermeable membrane in correlation with passage of time, to delay the delivery of said agglomeration of small wakeup agent subunits for a period of time corresponding to a nominal interval of sleep[~~; and~~].

60. (Previously Presented) A sleep pharmaceutical formulation for oral administration before bedtime, comprising:

a first component providing an neutral material having no pharmaceutical active material,

a second component containing at least one pharmaceutical wakeup agent, and

a third component for delaying the delivery of the wakeup agent of the second component for a period of time corresponding to a nominal interval of sleep.

61. (New) A sleep regulating pharmaceutical formulation for oral administration before bedtime, comprising:

an outer component providing an initial prompt release of a sleep-compatible substance for effecting onset of drowsiness and slumber,

an inner subsystem comprising a core containing a wakeup agent and a gas-generating substance;

said gas-generating substance generating gases upon reaction with water;

a coating comprising an osmotic semipermeable membrane impermeable to said wakeup agent covering said gas-generating substances;

said osmotic semipermeable membrane being permeable to water for enabling water in the

gastrointestinal tract to react with said gas-generating substance to progressively expand said osmotic semipermeable membrane in correlation with passage of time, to delay the delivery of said wakeup agent for a period of time; and

said osmotic semipermeable membrane and said gas-generating substance being selected to delay the delivery of said wakeup agent to prevent any overlap of the effects of said sleep-compatible substance and said wakeup agent.